

## **REMARKS**

### **I. Status of the Claims**

Prior to the present Office Action mailed 9/12/05, claims 21-56 were pending in the application and have been examined. Claims 22, 23, 31, 34, 35, 44-46 have been allowed. The present document amends claims 21, 24-27, and 53-56. No claims have been added. The current amendments are made and submitted to comply with stipulated requirements of form and clarity. The response faithfully incorporates the suggestions for amendments made by Examiner Jones during an interview with the Applicant & Inventor Rajindra Aneja on October 21, 2005. A copy of the claims is provided in the amendments section. According to 37 C.F.R. 1.116, after entry of the present amendment, the status of the claims in the case is as follows:

Claims 21-56 are therefore in the case.

### **Support for the Claims**

Support for the claims has been provided in the specification, and additionally is a matter of record in the Applicant's response mailed 6/17/05 that was responsive to the previous Office Action mailed 2/18/05. The present Office Action mailed 9/12/05 notes once again that no prior art has been cited against the instant invention, and that the claims are distinguished over the prior art of record for reasons of record in the Office Action mailed 2/18/05. Specific support for the currently amended claims is provided in the succeeding sections, especially sections II and III.

## II. 112 First Paragraph Rejection (New Matter)

Previously presented independent Claim 22, and original claims 23, 31, 34, 35, 44-46 dependent on claim 22, are drawn to C-phosphonate analogues of isotopically labelled phosphoinositide compounds; these claims have been allowed in the present Office Action mailed 9/12/05.

The previously presented independent claims 25, 27, and 54, (and claims 28, 38, 39, 47, 48 and 49 dependent on claim 25; claims 29, 42, 43, 50, 51, and 52 dependent on claim 27) are drawn to synthetic intermediate of isotopically labeled C-phosphonate analogue of a phosphoinositide compound; these claims are rejected in the present Office Action mailed 9/12/05, allegedly “on the basis that the structure appearing in claims 25, 27, and 54 are inconsistent with that of the disclosure (see page 5, line 1). Specifically, in the structures of the claims, there are two CH<sub>2</sub> groups attached to the phosphorous instead of one CH<sub>2</sub> group set forth in the disclosure.” Applicant respectfully traverses and submits that from the chemical perspective, the said structures are viewed merely as phosphoinositide analogues wherein one O–P bond of phosphate moiety of said phosphoinositide compound structure has been replaced by a C–P bond, exactly as required for the C-phosphonate analogue compound disclosed in the specification. Support for this is provided, for example, in the specification on page 9, lines 10-11. The Applicant thanks Examiner Jones for explicit guidance on the required form of the structure in these claims. Accordingly, in the interest of progressing the present claims and case to allowance, claims 25, 27 and 54 have been currently amended as follows: (1) deleting the structures with the “two CH<sub>2</sub> groups attached to the phosphorus” and (2) substituting therefor (i) the normal phosphoinositide structures, and, (ii) the stipulation in the text that in the said C-phosphonate compounds, an O-P bond of phosphate moiety of said phosphoinositide compound

structure is replaced by a C-P bond. The said stipulation is made by inserting, at the end of the claim, the phrase “; and wherein an O-P bond of phosphate moiety of said phosphoinositide compound structure is replaced by a C-P bond.”. Support for currently amended claims 25, 27 and 54 is provided, for example, in the specification on page 9, lines 10-11. Further, it will be noticed that the currently amended claims 25, 27 and 54 are modeled on, and are entirely consistent with, the allowed claim 22.

Rejected dependent claims 55 and 56 are drawn to C-phosphonate analogues of isotopically labelled phosphoinositide compounds. Claim 55 previously dependent on claim 22, and claim 56 previously dependent on claim 55, have been amended as follows: both are made dependent on allowed claim 22, and their distinguishing feature, C-P linking to glycerol residue and inositol residue respectively, previously shown in structural form, are now recited in the text. Specifically, in claim 55, the previously presented structure and the text starting in line 2 with “O-P bond link to glycerol in .....” have been deleted and replaced by the phrase “C-P bond linking is to the glycerol residue.” Similarly, in claim 56, the previously presented structure and the text starting in line 1 with “55 wherein the O-P bond link to inositol in .....” have been deleted and replaced by the phrase “22 wherein the C-P bond linking is to the inositol residue.” Support for claims 55 and 56 is provided, for example, in the specification on page 9, lines 10-11. The Applicant thanks Examiner Jones for guidance on the required form of the structure in these claims.

In addition to the amendments to claim 56 noted in the preceding paragraph, a previous typographic oversight has been corrected as follows: the phrase “C-” has been inserted between “(Currently amended) A” and “phosphonate analogue ...”. Thus, claim 56 now recites “A C-phosphonate analogue .....’ in conformity with the base claim 22, and the companion claim 55.

Original claims 28, 38, 39, 47, 48 and 49, dependent on claim 25; and, claims 29, 42, 43, 50, 51 and 52, dependent on claim 27; are consistent with the currently amended claims 25 and 27 respectively, and are retained unchanged.

It will thus be seen that the claims have been currently amended to represent the original description of the invention in the specification faithfully using terms that would be understood to have been disclosed in the original specification, and not to exclude a range of equivalents from the claims. Thus, all rejections under 35 U.S.C. 112, first paragraph are overcome and should be withdrawn.

### III. 112 Second Paragraph Rejection

The present Office Action states that the rejection of claims 21, 24, 26, 30, 32, 33, 36, 37, 40, 41 and 53 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the Office Action mailed 2/18/05 and those set out in the present Office Action.

A complete response to the reasons alleged in the 2/18/05 Office Action was presented in the Applicant's response mailed 6/17/05. Specifically, it was clarified that the complete sphingophosphoinositol structures shown in the independent claims 21, 24, 26 and 53 remained in the derivatives. Further, the ceramide and the sphingosine residues were identified as the part(s) of the structures that were derivatized. Moreover, the claimed structures were identified by the named derivatization reactions performed on the known functional groups in the ceramide and sphingosine residues.

The present Office Action introduces new questions about the effect of hypothetical removal of a CH<sub>2</sub> group, and, of two OH groups in combination with PO<sub>3</sub>. In response, the Applicant respectfully submits as follows: (1) the terms "ceramide residue" and "sphingosine residue" apply equally to respective backbone skeletal structures with varying numbers of skeletal CH<sub>2</sub> groups; and, (2) the two OH groups in combination with PO<sub>3</sub> are NOT part of the "ceramide residue" and "sphingosine residue" skeletal structures. As per the Examiner's guidance, in the interest of taking the said claims to allowance, claims 21, 24, 26, and 53 have been currently amended by deleting in each claim the phrase "or derivative of ceramide residue", and, "or derivative of sphingosine residue". It is believed that the said deletions put the currently amended claims in a form so that one may readily ascertain what is being claimed as desired by

the present Office Action. The applicant is grateful to Examiner Jones for suggesting the proper form of the aforementioned amendments comprising deletion of the phrases “or derivative of ceramide residue” and “or derivative of sphingosine residue”. Thus, the previously presented claims 21, 24, 26, and 53 have been revised to better define the invention in terms that more particularly point out and distinctly claim the unique features of the invention, and not to exclude a range of equivalents from the claims. Original claims 30, 32 and 33 dependent on claim 21; claims 36 and 37 dependent on claim 24; claims 40 and 41 dependent on claim 26, are consistent with the currently amended claims 21, 24 and 26 respectively, and are retained unchanged.

The rejections of claims 21, 24, 26, 30, 32, 33, 36, 37, 40, 41, and 53 under 35 U.S.C. 112, second paragraph are thus overcome and should be withdrawn.

#### **IV. Claims Objections**

The following original claims are retained unchanged: Claims 30, 32 and 33 (dependent on claim 21); claims 36 and 37 (dependent on claim 24); claims 28, 38, 39, 47, 48 and 49 (dependent on claim 25); claims 40 and 41 (dependent on claim 26); and, claims 29, 42, 43, 50, 51 and 52 (dependent on claim 27). These original claims are consistent with the currently amended base claims 21, 24, 25, 26, and 27 respectively. Further, currently amended dependent claims 55 and 56 are dependent on base claim 22 that has been allowed in the present Office Action mailed 9/12/05. The examiner's guidance on the aforementioned is appreciated. The Applicant respectfully submits that the aforementioned dependent claims 28, 29, 30, 32, 33, 36, 37, 38, 39, 40, 41, 42, 43, 47, 48, 49, 50, 51, 52, 55 and 56, are in a condition for allowance now.

## **V. Interview Summary**

A telephone interview between Examiner Dameron Levest Jones, and Applicant & Inventor Rajindra Aneja was held on October 21, 2005. Applicant thanked Examiner Jones for her participation and helpful suggestions for amending the rejected claims to place them in condition for allowance. It was agreed that the phrases “or derivative of ceramide” and “or derivative of sphingosine” be deleted from all previously presented claims that recited these phrases. In addition, it was agreed that structures showing “two CH<sub>2</sub> groups attached to the phosphorus” be deleted from all claims showing the said structures, and that the said structures be replaced by an equivalent description of C-phosphonate compound, the said description to comprise normal phosphoinositide type structure and/or a phrase indicating that an O-P bond of the normal phosphoinositide type structure has been replaced by a C-P bond. Details of the agreed to amendments to the previously presented claims 21, 24-27, 53-56, are as follows:

### **Amendments to Independent Claims 21, 24, 26, and 53:**

- (1) Delete the phrase “or derivative of ceramide residue”; and
- (2) Delete the phrase “or derivative of sphingosine residue”.

### **Amendments to Independent Claims 25, 27, and 54:**

- (1) Delete the structures with the “two CH<sub>2</sub> groups attached to the phosphorus”; and
- (2) Substitute therefor:
  - (i) The normal phosphoinositide type structures; and,
  - (ii) Add at the end of the claim, the phrase “; and wherein an O-P bond of phosphate moiety of said phosphoinositide compound structure is replaced by a C-P bond.”

**Amendments to Previously Presented Dependent Claim 55:**

1. Delete (i) the structure, and (ii) the text starting in line 2 with “O-P bond link to glycerol in .....”; and
2. Substitute therefor, the phrase: “C-P bond linking is to the glycerol residue.”

**Amendments to Previously Presented Dependent Claim 56:**

1. Delete (i) the structure, and (ii) the text starting in line 1 of the claim with the phrase; “55 wherein the O-P bond link to inositol in .....”, and
2. Substitute therefor: “22 wherein C-P bond linking is to the inositol residue.”

**Dependent Claims 28, 29, 30, 32, 33, 36-43, and 47-52:**

It was agreed that no amendments are necessary, and these original claims will be retained unchanged.

**Follow Up Actions:**

As agreement was reached on all outstanding claims, Examiner Jones indicated a willingness to allow the claims and enter all the claims, provided the mutually agreed-to amendments were filed with the US PTO before November 12, 2005.

## **VI. Formalities**

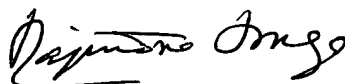
The inventor, Rajindra Aneja, Ph.D., is also the Director of the Assignee, Nutrimed Biotech. An Assignment is of record at reel **010115**, frame **0507**. The inventor/Applicant is now acting *pro se*. Please direct any correspondence to:

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## VII. Conclusion

In conclusion, Applicant submits that, in light of the foregoing remarks, the present case is in condition for allowance and such action is respectfully requested. Should Examiner Jones have any questions or comments, a telephone call to the undersigned Applicant is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Rajindra Aneja', written in a cursive style.

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Applicant & Inventor

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